



GA 1644

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Mouritsen and Elsner

Art Unit : Unknown

Serial No. : 08/955,373

Examiner : Unknown

Filed : Unknown

Title of corresponding

PCT application : INDUCING ANTIBODY RESPONSE AGAINST SELF-  
PROTEINS WITH THE AID OF FOREIGN T-CELL EPITOPES

TECH CENTER 1600/2900

7-7-00

#27

Commissioner for Patents

Washington, D.C. 20231

TRANSMITTAL LETTER

Enclosed are the following documents for filing:

1. Protest under 37 C.F.R. §1.291(a)
2. Copies of the following references
  - EP 0 752 886 B1 ✓
  - PCT DK/94/00318 ✓
  - WO 93/05810 ✓ D
3. Postcard

A duplicate of this Protest is being sent to the applicant's attorney.

Respectfully Submitted,

Date: June 16, 2000

Mark S. Ellinger  
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Reg. No. 34,812

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CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, Washington, D.C. 20231.

June 16, 2000  
Date of Deposit

Jill Huso  
Signature

Jill Huso  
Typed or Printed Name of Person Signing Certificate



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PROTEST UNDER 37 C.F.R. §1.291(a)

Resistentia Pharmaceuticals AB respectfully submits the following protest against the above-referenced U.S. Patent Application under 37 C.F.R. §1.291(a). Resistentia Pharmaceuticals AB is a Swedish company actively working to develop IgE vaccines that will help people with allergy problems. Resistentia Pharmaceuticals AB has learned of a European Patent EP 0 752 886 B1 granted to Mouritsen and Elsner on January 28, 1998. EP 0 752 886 B1 is believed to be a national phase filing from PCT DK/94/00318. Analysis of this European Patent revealed significant deficiencies that render the patent invalid, prompting Resistentia Pharmaceuticals AB to file a revocation proceeding against EP 0 752 886 B1 in Sweden. This proceeding is directed to the validity of EP 0 752 886 B1 and has case number T 5769/00.

Like EP 0 752 886 B1, the above-referenced U.S. Patent Application is believed to be a national phase filing from PCT DK/94/00318. PCT DK/94/00318 describes methods and compositions related to the modification of self-proteins to induce antibody responses against the body's own proteins. The predominant self-protein modification described in PCT DK/94/00318 relates to the insertion of one or more immunodominant T cell epitopes into a self-protein, exemplified by inserting a short peptide sequence into ubiquitin and TNF $\alpha$ . The claims of the above-referenced U.S. Patent Application are believed to be similar to the claims presented in PCT DK/94/00318.

Resistentia Pharmaceuticals AB would like to draw the Examiner's attention to WO 93/05810, which was published April 1, 1993. WO 93/05810 is prior art to the above-referenced U.S. Patent Application under 35 U.S.C. §102(b). This is because (1)

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the actual U.S. filing date of the above-referenced U.S. Patent Application is August 25, 1994, not the Danish priority date of August 26, 1993, and (2) WO 93/05810 published more than one year before August 25, 1994. According to 35 U.S.C. §119(a), "no patent shall be granted on any application for patent for an invention which had been patented or described in a printed publication in any country more than one year before the date of the actual filing of the application in this country . . . ."

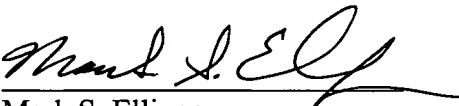
WO 93/05810 is particularly relevant to the subject matter disclosed in the above-referenced U.S. Patent Application. WO 93/05810 discloses that a self-protein (e.g., IgE) can be mutated by additions, deletions, insertions, or substitutions to create a modified protein that induces an antibody response against the body's own protein. It is important to note that WO 93/05810 states that heavily mutated self-proteins can be made by "exchange, deletion and/or insertion of amino acids." See, WO 93/05810 page 5, lines 29-30. The alteration of ubiquitin and TNF $\alpha$  as described in the above-referenced U.S. Patent Application is a straightforward example of heavily mutating a self-protein as taught by WO 93/05810. This is especially true since the sole objective is to induce an antibody response against a self-protein. Claims relating generally to the modification of self-proteins are anticipated and obvious in light of WO 93/05810 since a person having ordinary skill in the art would have appreciated that the subject matter of such claims was previously taught in WO 93/05810. In light of the teachings in WO 93/05810, any claims in the above-referenced U.S. Patent Application relating to the modification of a self-protein by additions, deletions, insertions, or substitutions so that a modified protein is created that induces an antibody response against the body's own protein should be rejected as anticipated and obvious.

For the Examiner's convenience, copies of EP 0 752 886 B1, PCT DK/94/00318 and WO 93/05810 are enclosed.

Please apply any charges or credits to Deposit Account No. 06-1050.

Date: June 16, 2000



Respectfully submitted,  
  
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